

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Tetracycline Hydrochloride

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
4.0	06/20/2025	5479501-00012	Date of first issue: 03/05/2020

### SECTION 1. IDENTIFICATION

Product name : Tetracycline Hydrochloride  
Product code : Tetracycline hydrochloride, Tetracycline hydrochloride

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

Reproductive toxicity : Category 1A

Effects on or via lactation

Specific target organ toxicity : Category 2 (Gastrointestinal tract, Nervous system, Skin, Teeth)  
- repeated exposure (Oral)

#### Other hazards

Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.

#### GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.  
H360D May damage the unborn child.  
H362 May cause harm to breast-fed children.  
H373 May cause damage to organs (Gastrointestinal tract, Nervous system, Skin, Teeth) through prolonged or repeated exposure if swallowed.

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**Precautionary Statements :**

**Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe dust.  
P263 Avoid contact during pregnancy and while nursing.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P280 Wear protective gloves, protective clothing, eye protection and face protection.

**Response:**  
P308 + P313 IF exposed or concerned: Get medical attention.

**Storage:**  
P405 Store locked up.

**Disposal:**  
P501 Dispose of contents and container to an approved waste disposal plant.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Substance  
Substance name : Tetracycline hydrochloride  
CAS-No. : 64-75-5

#### Components

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
Tetracycline hydrochloride	64-75-5*	>= 80 - <= 100	TSC

\* Indicates that the identifier is a CAS No.

TSC- the actual concentration or concentration range is withheld as a trade secret

### SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.  
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.

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In case of eye contact	: If in eyes, rinse well with water. Get medical attention if irritation develops and persists.
If swallowed	: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	: Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation. May damage the unborn child. May cause harm to breast-fed children. May cause damage to organs through prolonged or repeated exposure if swallowed.
Protection of first-aiders	: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	: Treat symptomatically and supportively.

### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	: None known.
Specific hazards during fire fighting	: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: Carbon oxides Nitrogen oxides (NO <sub>x</sub> ) Chlorine compounds
Specific extinguishing methods	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	: Avoid release to the environment.

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Prevent further leakage or spillage if safe to do so.  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### SECTION 7. HANDLING AND STORAGE

Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Avoid contact during pregnancy and while nursing.  
Do not get on skin or clothing.  
Do not breathe dust.  
Do not swallow.  
Avoid contact with eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labeled containers.  
Store locked up.  
Keep tightly closed.  
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides

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Explosives  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

inert or nuisance dust	50 Million particles per cubic foot
	Value type (Form of exposure): TWA (total dust)
	Basis: OSHA Z-3
	15 mg/m <sup>3</sup>
	Value type (Form of exposure): TWA (total dust)
	Basis: OSHA Z-3
	5 mg/m <sup>3</sup>
	Value type (Form of exposure): TWA (respirable fraction)
	Basis: OSHA Z-3
	15 Million particles per cubic foot
	Value type (Form of exposure): TWA (respirable fraction)
	Basis: OSHA Z-3
Dust, nuisance dust and particulates	10 mg/m <sup>3</sup>
	Value type (Form of exposure): PEL (Total dust)
	Basis: CAL PEL
	5 mg/m <sup>3</sup>
	Value type (Form of exposure): PEL (respirable dust fraction)
	Basis: CAL PEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Tetracycline hydrochloride	64-75-5	TWA	0.9 mg/m <sup>3</sup> (OEB 2)	Internal

**Engineering measures** : Use feasible engineering controls to minimize exposure to compound.  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

#### Personal protective equipment

**Respiratory protection** : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled

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	release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.
Hand protection Material	: Chemical-resistant gloves
Eye protection	: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection Hygiene measures	: Work uniform or laboratory coat. : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: Crystalline powder
Color	: No data available
Odor	: No data available
Odor Threshold	: No data available
pH	: No data available
Melting point/freezing point	: 417 °F / 214 °C
Initial boiling point and boiling range	: No data available
Flash point	: No data available
Evaporation rate	: Not applicable
Flammability (solid, gas)	: May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	: Not applicable
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower	: No data available

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flammability limit

Vapor pressure : Not applicable

Relative vapor density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : 0.231 g/l

Partition coefficient: n-octanol/water : log Pow: -1.37  
pH: 7

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : 480.9 g/mol

Particle characteristics

Particle size : No data available

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### SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.  
Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

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### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

##### Tetracycline hydrochloride:

Acute oral toxicity	:	LD50 (Rat): 6,443 mg/kg
		LD50 (Mouse): 2,759 mg/kg
Acute toxicity (other routes of administration)	:	LD50 (Rat): 128 mg/kg
		Application Route: Intravenous
		LD50 (Mouse): 157 mg/kg
		Application Route: Intravenous

#### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### Tetracycline hydrochloride:

Remarks	:	No data available
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#### Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

##### Tetracycline hydrochloride:

Remarks	:	No data available
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#### Respiratory or skin sensitization

##### Skin sensitization

Not classified based on available information.

##### Respiratory sensitization

Not classified based on available information.

#### Components:

##### Tetracycline hydrochloride:

Remarks	:	No data available
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### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### Tetracycline hydrochloride:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: Cytogenetic assay Test system: Chinese hamster ovary cells Result: negative
		Test Type: sister chromatid exchange assay Result: negative
		Test Type: Mouse Lymphoma Result: negative

### Carcinogenicity

Not classified based on available information.

#### Components:

##### Tetracycline hydrochloride:

Species	:	Rat
Application Route	:	Oral
Exposure time	:	103 W
Result	:	negative
Species	:	Mouse
Application Route	:	Oral
Exposure time	:	103 W
Result	:	negative

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### Reproductive toxicity

May damage the unborn child.  
May cause harm to breast-fed children.

#### Components:

##### Tetracycline hydrochloride:

Effects on fertility	:	Test Type: Fertility Species: Rat
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	Application Route: Oral
	Fertility: NOAEL: 400 mg/kg body weight
	Result: No effects on fertility.
Effects on fetal development	: Test Type: Development
	Result: Embryo-fetal toxicity., Specific developmental abnormalities., Skeletal malformations.
Reproductive toxicity - Assessment	: Studies indicating a hazard to babies during the lactation period, May damage the unborn child.

### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

May cause damage to organs (Gastrointestinal tract, Nervous system, Skin, Teeth) through prolonged or repeated exposure if swallowed.

### Components:

#### Tetracycline hydrochloride:

Routes of exposure	: Oral
Target Organs	: Gastrointestinal tract, Nervous system, Skin, Teeth
Assessment	: May cause damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

### Components:

#### Tetracycline hydrochloride:

Species	: Rat
NOAEL	: 625 mg/kg
LOAEL	: 1,250 mg/kg
Application Route	: oral (feed)
Exposure time	: 13 W
Target Organs	: Liver
Symptoms	: Reduced body weight

Species	: Mouse
NOAEL	: 3,750 mg/kg
LOAEL	: 7,500 mg/kg
Application Route	: oral (feed)
Exposure time	: 13 W
Symptoms	: Reduced body weight

### Aspiration toxicity

Not classified based on available information.

### Components:

#### Tetracycline hydrochloride:

Not applicable

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### Experience with human exposure

#### Components:

##### Tetracycline hydrochloride:

Ingestion	: Target Organs: Teeth Symptoms: Gastrointestinal disturbance, Nausea, Vomiting, Diarrhea, Liver effects, skin rash, central nervous system effects Remarks: May cause sensitization of susceptible persons. May cause photosensitization. Based on Human Evidence
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## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

##### Tetracycline hydrochloride:

Toxicity to algae/aquatic plants	: EC50 (Anabaena flos-aquae (cyanobacterium)): 6.2 mg/l Exposure time: 72 h  NOEC (Anabaena flos-aquae (cyanobacterium)): 2.5 mg/l Exposure time: 72 h  EC50 (Pseudokirchneriella subcapitata (green algae)): 3.31 mg/l Exposure time: 72 h  NOEC (Pseudokirchneriella subcapitata (green algae)): 0.032 mg/l Exposure time: 72 h  EC50 (Microcystis aeruginosa (blue-green algae)): 0.09 mg/l Exposure time: 7 d
Toxicity to microorganisms	: EC50: 0.08 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209

### Persistence and degradability

No data available

### Bioaccumulative potential

#### Components:

##### Tetracycline hydrochloride:

Partition coefficient: n-octanol/water	: log Pow: -1.37 pH: 7
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### II

#### Mobility in soil

No data available

#### Other adverse effects

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

Waste from residues	:	Dispose of in accordance with local regulations. Do not dispose of waste into sewer.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

## SECTION 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (tetracycline hydrochloride)
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	yes

##### IATA-DGR

UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Tetracycline hydrochloride)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	956
Packing instruction (passenger aircraft)	:	956
Environmentally hazardous	:	yes

##### IMDG-Code

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Tetracycline hydrochloride)
Class	:	9
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

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### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

### Domestic regulation

#### 49 CFR

UN/ID/NA number	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Tetracycline hydrochloride)
Class	:	9
Packing group	:	III
Labels	:	CLASS 9
ERG Code	:	171
Marine pollutant	:	yes(Tetracycline hydrochloride)
Remarks	:	Above applies only to containers over 119 gallons or 450 liters. Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

## SECTION 15. REGULATORY INFORMATION

### CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

<b>SARA 311/312 Hazards</b>	:	Combustible dust Reproductive toxicity Specific target organ toxicity (single or repeated exposure)
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<b>SARA 313</b>	:	The following components are subject to reporting levels established by SARA Title III, Section 313:
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Tetracycline hydrochloride	64-75-5	>= 90 - <= 100 %
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### US State Regulations

#### Pennsylvania Right To Know

Tetracycline hydrochloride	64-75-5
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### California Prop. 65

WARNING: This product can expose you to chemicals including Tetracycline hydrochloride, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

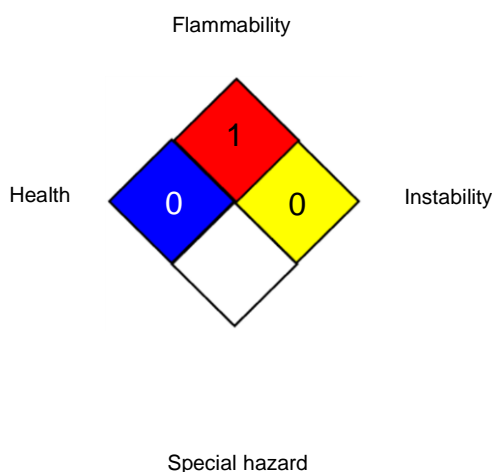
### The ingredients of this product are reported in the following inventories:

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

## SECTION 16. OTHER INFORMATION

### Further information

#### NFPA 704:



#### HMIS® IV:

HEALTH	*	4
FLAMMABILITY		3
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### Full text of other abbreviations

CAL PEL	:	California permissible exposure limits for chemical contaminants (Title 8, Article 107)
OSHA Z-3	:	USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
CAL PEL / PEL	:	Permissible exposure limit
OSHA Z-3 / TWA	:	8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with

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x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECL - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 06/20/2025

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

US / Z8